

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

LOUISIANA WHOLESALE DRUG CO.,	)	
	)	
Plaintiff,	)	
vs.	)	Civil Action No.: 07-CIV-7343 (HB)
	)	
SANOFI-AVENTIS, SANOFI-AVENTIS	)	
U.S. LLC and AVENTIS	)	ORAL ARGUMENT REQUESTED
PHARMACEUTICALS, INC.	)	
Defendants.	)	
	)	
	)	
	)	

---

**THIRD PARTY SANDOZ INC.'S MOTION TO QUASH SUBPOENA**

Pursuant to Fed. R. Civ. P. 45, third party Sandoz, Inc. hereby objects and moves to quash the subpoena dated October 22, 2007 ("Subpoena"), which plaintiff, Louisiana Wholesale Drug co. ("Louisiana Wholesale") served in connection with the above – captioned matter.

**I. FACTS RELATING TO THIS MOTION**

On or about August 17, 2007, Louisiana Wholesale filed a class action complaint in this Court seeking treble damages from defendants (collectively "Aventis") for violating the antitrust laws by filing a baseless Citizen Petition with the FDA for the purpose of delaying the FDA's approval of generic versions of the drug leflunomide marketed by Aventis under the trade name "Arava." A copy of the complaint is attaché to the Declaration of Edward Reisner ("Reisner Decl.") as Exhibit A. According to the complaint, once the FDA receives a Citizen Petition relating to a pending Abbreviated New Drug Application ("ANDA"), it will withhold approval of the ANDA until it has resolved the issues raised in the Citizen Petition. Plaintiff alleges that the result of Aventis's filing its meritless Citizen Petition (in March, 2005) was to delay for five months approval of ANDA's to market generic versions of Arava that had been filed by a number of drug companies including, Kali Laboratories, Barr Laboratories, TEVA

Pharmaceuticals, Apotex Corp. and Sandoz, which enabled Aventis to continue selling Arava at the elevated prices its market exclusivity permitted. *See* Complaint ¶7 The complaint alleges that, once the FDA denied Aventis's Citizen Petition on September 13, 2005, generic versions of leflunomide immediately entered the market and Aventis lost 80% of its market share within three months. *See* Complaint ¶8. . On or about October 17, 2007, defendants filed a motion to dismiss the complaint, which is still pending.

On or about October 22, 2007, Louisiana Wholesale served Sandoz with a subpoena which, in essence, required Sandoz to produce and permit inspection of virtually every single document in its custody or control referring or relating to the development of its generic version of Arava and its dealings with the FDA including, *inter alia*, all documents referring or relating to: Arava; "any Citizen Petition filed regarding leflunomide;" "plans for launching leflunomide...including launch updates, timelines, schedules, asset allocation analysis, sales forecasts...and commercial production;" Sandoz's ANDA and all correspondence with the FDA; development of Sandoz's formulation of leflunomide including "agendas and minutes of meetings" relating to that broad topic; all sales data (in units and dollars per package and dollars per unit) relating to leflunomide products identifying the customers, numbers of packages sold, returned, etc., price and unit adjustments; all IMS data (or other third-party generated marketing information) relating to leflunomide; all marketing forecasts; organization charts and telephone directories for the entire company and for each division or affiliate that had or has any involvement in the research, development, regulatory approval, manufacture, sale or marketing of any leflunomide product, etc. A copy of the subpoena is attached as Reisner Decl. Exhibit B. The subpoena also required Sandoz to appear for a deposition on December 17, 2007 at the offices of Garwin, Gerstein & Fisher LLP, 1501 Broadway, Suite 1416, New York, N.Y.

On or about November 6, 2007, counsel for Sandoz contacted Anne Fornecker, Esq., at Garwin, Gerstein (who had signed the subpoena), and requested that they withdraw the subpoena, which was clearly overly broad considering the issues in the litigation. *See* Reisner Decl. ¶ 9. Ms Fornecker conceded that the subpoena was overly broad and said that plaintiffs' counsel (there are at least seven different firms representing various

plaintiffs' groups) would be having a discussion concerning "what they really needed" and would advise Sandoz counsel after that meeting was held. *Id.* ¶10.

On or about November 9, 2007, Sandoz's counsel participated in a conference call with a number of plaintiffs' lawyers, who provided their reasons for the breadth of their subpoena. While agreeing that the main issue was whether Sandoz would have been ready, willing and able to launch its generic leflunomide in April, 2005, but for the filing of the Citizen Petition, they conceded that they were asking for more documents and information than needed to make their case. *Id.* ¶11. They justified that overbreadth because; (a) they did not know what level of proof the judge would subject them to; and (b) they did not know what defenses Aventis would raise. *Id.*

On or about November 14, 2007, Sandoz's counsel advised plaintiffs' counsel that Sandoz had still been negotiating with the FDA regarding technical issues relating to its ANDA which were not resolved until September 12, 2005. *See* Reisner Decl. ¶12. Thus, it is clear that the Citizen Petition only delayed approval of Sandoz's ANDA, at most, by one day and that Sandoz's "delay" would be irrelevant to any damages that the plaintiffs would be awarded if they prevailed in their suit. *Id.*

Given that fact, the pendency of the motion to dismiss and the fact that a scheduling order had not even been entered yet in the case, Sandoz's counsel again requested that plaintiffs withdraw their overly broad subpoena. Sandoz's counsel also pointed out that, even though plaintiffs had expressed a willingness to somewhat narrow the scope of the subpoena (inadequately in Sandoz's view), as long as the subpoena was the operative document, no side-deal cut with plaintiffs would shield Sandoz from possible sanctions for noncompliance with its terms if Aventis objected, which was likely given that Sandoz information would be helpful primarily to them. *Id.* ¶13.

Although plaintiffs' counsel said that they would consider Sandoz's request and provide a response, none has been received. *Id.* Meanwhile, counsel for Sandoz has learned that the principle witness who would be designated by Sandoz, Beth Brannan, Sandoz Director of Regulatory Affairs, resides in Broomfield, Colorado, which also is where many of the documents sought by the subpoena are located. *Id.* 14.

## II. ARGUMENT

Fed. R. Civ. P. 45(c)(3)(A)(ii) states that the court that issued a subpoena “shall quash or modify it if the subpoena...requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business...” Given that the individual that Sandoz would likely designate as its witness to address the FDA approval of its generic Arava lives and works in Colorado, the plain language of Rule 45 mandates that the subpoena be quashed.

Rule 45 also permits the court to quash or modify if it subjects a person to “undue burden.” In this case there can be no doubt that compliance with the subpoena served on Sandoz would subject it to undue burden to provide reams of documents virtually none of which would be relevant to any issue in the underlying lawsuit. The principle issues that the plaintiffs must prove to make their case are that: (1) but for the Citizen Petition, the generic drug companies with pending ANDA’s would have received approval to market their generic versions of Arava significantly sooner than the actual date of FDA approval of September 13, 2007; (2) that they would have been ready, willing and able to have launched at that earlier date; (3) that the arrival of one or more generic versions of Arava on the market would have led to a precipitous drop in the price charged to the plaintiffs for the drug by Aventis; and (4) that Aventis knew that its Citizen Petition was baseless but filed it anyway in order to delay the approval of generic Arava. Sandoz has no knowledge concerning the other generic manufacturers dealings with the FDA, but can (and will) demonstrate that, because it was still addressing technical issues with the FDA that necessitated filing an Amendment to its ANDA on September 8, 2007 which was accepted and deemed to place the ANDA in condition for approval by September 12, 2007. The documents evidencing these facts speak for themselves and can be authenticated by an interrogatory response or a few written deposition questions. In view of those facts, none of the other documents or information sought by plaintiffs would be relevant to any issue in the case.

Even if Sandoz’s approval had, in fact, been delayed by the Citizen Petition, however, the subpoena served by the plaintiffs would still warrant quashing or at least severe modification, since it seeks numerous documents and information unrelated to any issue in the case. Whatever Sandoz’s projections concerning its sales once it entered the market might have been, those projections are nothing but that – educated guesses about

the future by Sandoz personnel. The actual sales and the effect on price that Sandoz's entry into the market actually had in the six months immediately following its launch would have been the only facts bearing on the plaintiffs' possible damages if Sandoz's entry into the market had actually been delayed by the Citizen Petition. Similarly, none of the information concerning Sandoz's development of its formulation or its dealings with the FDA prior to March, 2005 are relevant to any issue. Obviously, Sandoz's entire ANDA and related documents are similarly irrelevant. The list of unnecessary documents that Sandoz has been asked to produce goes on and on.

Although plaintiffs may well come up with some arguments justifying some of their broad requests, they will be, for the most part, based on nothing more than speculation concerning arguments that Aventis might make. Whatever arguments plaintiffs raise, however, cannot overcome the simple fact that Sandoz would not have received approval of its ANDA before September 12, 2007, even if Aventis had not filed a Citizen Petition.

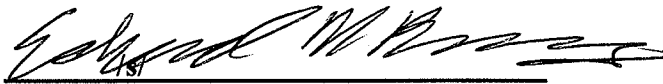
Sandoz understands that it has information that is relevant to this litigation and is perfectly willing to provide it. But to require Sandoz to go through dozens of individuals' emails, letters, notebooks and other files to locate and copy responsive documents and then to require Sandoz to pay for its counsel to review all such documents for privileged, proprietary and nonresponsive material to redact and or withhold and list on a privileged document log would be unconscionable. The time and expense that Sandoz would expend in attempting to comply with the subpoena plaintiffs served would not only be extreme, but would be grossly disproportionate to the limited amount of truly relevant factual information that would be discovered.

### **CONCLUSION**

Sandoz, therefore, respectfully requests that the Court enter an order quashing plaintiffs' subpoena and permitting Sandoz to provide to both plaintiffs and defendants copies of the relevant documents from its FDA files demonstrating that approval of its ANDA was not delayed by Aventis' Citizen Petition together with an affidavit authenticating those documents. After reviewing those documents, both plaintiff and defendants should then be permitted to conduct a deposition on written questions limited

strictly to those documents relating to the FDA's approval of Sandoz's ANDA. This will permit the parties to satisfy themselves that Sandoz's activities are simply not pertinent

Dated: November 26, 2007



Edward M. Reisner (ER-3934)

**COHEN PONTANI LIEBERMAN & PAVANE LLP**

551 Fifth Avenue, Suite 1210

New York, New York 10176

(212) 687-2770

(212) 972-5487 (fax)

*Attorneys for Sandoz, Inc.*

#### **CERTIFICATE OF SERVICE**

I hereby certify that Sandoz's Inc.'s Motion to Quash Subpoena, Declaration of Edward M. Reisner and Exhibits A and B thereto were served by ECF on:

**Garwin Gerstein & Fisher LLP**

1501 Broadway, Suite 1416

New York, NY 10036

Ph. 212 398-0055

Fx. 212 764-6620

**Counsel for Plaintiff, Louisiana Wholesale Drug Co.**

Dated: November 27, 2007



Cindy Babbitt